

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

AMY W. SCHULMAN
DLA PIPER LLP
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 335-4500
Facsimile: (212) 335-4501
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)
GORDON & REES LLP
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

MICHAEL C. ZELLERS (SBN: 146904)
TUCKER ELLIS & WEST LLP
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com

Attorneys for Defendant
PFIZER INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

RAYMOND LAWRENCE,

Plaintiff,

vs.

PFIZER, INC.,

Defendant.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-1172-CRB

) **PFIZER INC.'S ANSWER TO
COMPLAINT**

) **JURY DEMAND ENDORSED
HEREIN**

1 NOW COMES Defendant Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer" or "Defendant") and files this Answer to Plaintiff's Complaint
3 ("Complaint"), and would respectfully show the Court as follows:

4 **I.**

5 **PRELIMINARY STATEMENT**

6 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
7 Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally.
8 Defendant may seek leave to amend this Answer when discovery reveals the specific time
9 periods in which Plaintiff was prescribed and used Bextra®.

10 **II.**

11 **ANSWER**

12 **Response to Allegations Regarding Parties**

13 1. Defendant admits that Plaintiff brought this civil action seeking monetary damages, but
14 denies that Plaintiff is entitled to any relief or damages. Defendant admits that, during certain
15 periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States
16 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendant admits that, during certain periods of
18 time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,
19 co-promoted and distributed Bextra® in the United States to be prescribed by healthcare
20 providers who are by law authorized to prescribe drugs in accordance with their approval by the
21 FDA. Defendant states that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendant states that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or damage,
26 and denies the remaining allegations in this paragraph of the Complaint.

27 2. Defendant is without knowledge or information sufficient to form a belief as to the truth
28 of the allegations regarding Plaintiff's age and citizenship, and, therefore, denies the same.

1 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
2 allegations regarding whether Plaintiff used Bextra® and Plaintiff's medical condition, and,
3 therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the
4 Complaint.

5 3. Defendant admits that Pfizer is a Delaware corporation with its principal place of
6 business in New York. Defendant admits that Pharmacia acquired Searle in 2000 and that, as
7 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
8 Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
9 Bextra® in the United States, including California, to be prescribed by healthcare providers
10 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
11 Defendant states that Plaintiff's allegations regarding "predecessors in interest" are vague and
12 ambiguous. Defendant is without knowledge or information to form a belief as to the truth of
13 such allegations, and, therefore, denies the same. Defendant denies the remaining allegations in
14 this paragraph of the Complaint.

15 **Response to Allegations Regarding Jurisdiction and Venue**

16 4. Defendant is without knowledge or information to form a belief as to the truth of the
17 allegations in this paragraph of the Complaint regarding the amount in controversy, and,
18 therefore, denies that the same. However, Defendant admits that Plaintiff claims that the
19 amount in controversy exceeds \$75,000, exclusive of interests and costs.

20 5. Defendant is without knowledge or information sufficient to form a belief as to the truth
21 of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and the
22 amount in controversy, and, therefore, denies the same. However, Defendant admits that
23 Plaintiff claims that the parties are diverse and that the amount in controversy exceeds \$75,000,
24 exclusive of interests and costs.

25 6. Defendant is without knowledge or information sufficient to form a belief as to the truth
26 of the allegations in this paragraph of the Complaint regarding the judicial district in which the
27 asserted claims allegedly arose, and, therefore, denies the same. Defendant denies committing
28 a tort in the State of Kansas or the State of California and denies the remaining allegations in

1 this paragraph of the Complaint.

2 7. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed
3 and co-promoted Bextra® in the United States, including California and Louisiana, to be
4 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
5 with their approval by the FDA. Defendant admits that, during certain periods of time, Bextra®
6 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
7 and distributed Bextra® in the United States to be prescribed by healthcare providers who are
8 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
9 admits that they provided FDA-approved prescribing information regarding Bextra®.
10 Defendant admits that they do business in the State of California. Defendant states that
11 Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendant
12 is without knowledge or information to form a belief as to the truth of such allegations, and,
13 therefore, denies the same. Defendant denies any wrongful conduct and denies the remaining
14 allegations in this paragraph of the Complaint.

15 **Response to Allegations Regarding Interdistrict Assignment**

16 8. Defendant states that this paragraph of the Complaint contains legal contentions to
17 which no response is required. To the extent that a response is deemed required, Defendant
18 admits that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
19 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
20 Panel on Multidistrict Litigation on September 6, 2005.

21 **Response to Factual Allegations**

22 9. Defendant is without knowledge or information sufficient to form a belief as to the truth
23 of the allegations regarding Plaintiff's medical condition and whether Plaintiff used Bextra®
24 and, therefore, denies the same. Defendant denies any wrongful conduct, denies that Bextra®
25 caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
26 Complaint.

27 10. Defendant admits that Bextra® was expected to reach consumers without substantial
28 change from the time of sale. Defendant is without knowledge or information sufficient to form

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1 a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and,
2 therefore, denies the same. Defendant denies the remaining allegations this paragraph of the
3 Complaint.

4 11. Defendant states that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendant states that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
9 allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
10 Defendant denies remaining the allegations in this paragraph of the Complaint.

11 12. Defendant admits that Bextra® is in a class of drugs that is, at times, referred to as non-
12 steroidal anti-inflammatory drugs (“NSAIDS”). Defendant states that Bextra® was and is safe
13 and effective when used in accordance with its FDA-approved prescribing information.
14 Defendant states that the potential effects of Bextra® were and are adequately described in its
15 FDA-approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendant denies the remaining allegations in this
17 paragraph of the Complaint.

18 13. The allegations in this paragraph of the Complaint are not directed toward Defendant
19 and, therefore, no response is required. To the extent a response is deemed required, Defendant
20 states that Plaintiff fails to provide the proper context for the allegations in this paragraph of the
21 Complaint. Defendant therefore lacks sufficient information or knowledge to form a belief as
22 to the truth of such allegations and, therefore, denies the same.

23 14. The allegations in this paragraph of the Complaint are not directed toward Defendant
24 and, therefore, no response is required. To the extent a response is deemed required, Defendant
25 states that Plaintiff fails to provide the proper context for the allegations in this paragraph of the
26 Complaint. Defendant therefore lacks sufficient information or knowledge to form a belief as
27 to the truth of such allegations and, therefore, denies the same.

28 15. The allegations in this paragraph of the Complaint are not directed toward Defendant

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1 and, therefore, no response is required. To the extent a response is deemed required, Defendant
2 states that Plaintiff fails to provide the proper context for the allegations in this paragraph of the
3 Complaint. Defendant therefore lacks sufficient information or knowledge to form a belief as
4 to the truth of such allegations and, therefore, denies the same.

5 16. The allegations in this paragraph of the Complaint are not directed toward Defendant
6 and, therefore, no response is required. To the extent a response is deemed required, Defendant
7 states that Plaintiff fails to provide the proper context for the allegations in this paragraph of the
8 Complaint. Defendant therefore lacks sufficient information or knowledge to form a belief as
9 to the truth of such allegations and, therefore, denies the same.

10 17. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
11 Complaint. Defendant lacks sufficient information or knowledge to form a belief as to the truth
12 of such allegations and, therefore, denies the same.

13 18. Defendant states that Plaintiff's allegations regarding "predecessors in interest" are
14 vague and ambiguous. Defendant is without knowledge or information to form a belief as to
15 the truth of such allegations, and, therefore, denies the same. Defendant denies any wrongful
16 conduct and denies the remaining allegations in this paragraph of the Complaint.

17 19. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless,
18 Defendant admits that Celebrex® was launched in the United States in February 1999.
19 Defendant states that Celebrex® was and is safe and effective when used in accordance with its
20 FDA-approved prescribing information. Defendant admits that, during certain periods of time,
21 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
22 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
23 with their approval by the FDA. Defendant admits that, during certain periods of time,
24 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
25 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
26 providers who are by law authorized to prescribe drugs in accordance with their approval by the
27 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not
28 directed toward Defendant and, therefore, no response is required. To the extent a response is

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1 deemed required, Defendant states that Plaintiff fails to provide the proper context for the
2 allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendant
3 therefore lacks sufficient information or knowledge to form a belief as to the truth of such
4 allegations and, therefore, denies the same. Defendant denies the remaining allegations in this
5 paragraph of the Complaint.

6 20. Defendant admits that the New Drug Application for Bextra® was filed with the FDA
7 on January 15, 2001. Defendant admits, as indicated in the package insert approved by the
8 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis
9 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant
10 states that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous.
11 Defendant is without knowledge or information to form a belief as to the truth of such
12 allegations, and, therefore, denies the same. Defendant denies the remaining allegations in this
13 paragraph of the Complaint.

14 21. Defendant admits that Bextra® was approved by the FDA on November 16, 2001.
15 Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is
16 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
17 arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining
18 allegations in this paragraph of the Complaint.

19 22. Defendant admits, as indicated in the package insert approved by the FDA, that Bextra®
20 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
21 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies
22 the remaining allegations in this paragraph of the Complaint.

23 23. Defendant admits, as indicated in the package insert approved by the FDA, that Bextra®
24 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
25 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant states
26 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
27 prescribing information. Defendant states that the potential effects of Bextra® were and are
28 adequately described in its FDA-approved prescribing information, which at all times was

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adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

24. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendant is without knowledge or information to form a belief as to the truth of such allegations, and, therefore, denies the same. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

25. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies any wrongful conduct and denies the

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1 remaining allegations in this paragraph of the Complaint.

2 26. Defendant states that the referenced article speaks for itself and respectfully refers the
3 Court to the article for its actual language and text. Any attempt to characterize the article is
4 denied. Defendant states that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendant denies the remaining allegations in
6 this paragraph of the Complaint.

7 27. The allegations in this paragraph of the Complaint are not directed toward Defendant
8 and, therefore, no response is necessary. Should a response be deemed necessary, Defendant
9 states that the referenced article speaks for itself and respectfully refers the Court to the article
10 for its actual language and text. Any attempt to characterize the article is denied. Defendant
11 denies the remaining allegations in this paragraph of the Complaint.

12 28. Defendant admits that the New Drug Application for Bextra® was filed with the FDA
13 on January 15, 2001. Defendant admits that Bextra® was approved by the FDA, on November
14 16, 2001. Defendant denies any wrongful conduct and the remaining allegations in this
15 paragraph of the Complaint.

16 29. Defendant states that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendant states that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which at all times was adequate and comported with applicable standards of care and law.
20 Defendant denies the allegations in this paragraph of the Complaint.

21 30. Defendant states that the referenced FDA Talk Paper for Bextra® speaks for itself and
22 respectfully refers the Court to the Talk Paper for its actual language and text. Any attempt to
23 characterize the Talk Paper is denied. Defendant denies the remaining allegations in this
24 paragraph of the Complaint.

25 31. Defendant states that the referenced article speaks for itself and respectfully refers the
26 Court to the article for its actual language and text. Any attempt to characterize the article is
27 denied. Defendant denies the remaining allegations in this paragraph of the Complaint.

28 32. Plaintiff fails to provide the proper context for the allegations concerning the “post-drug

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1 approval meta-analysis study” in this paragraph of the Complaint. Defendant is without
2 sufficient information to confirm or denies such allegations and, therefore, denies the same.
3 Defendant states that the referenced study speaks for itself and respectfully refers the Court to
4 the study for its actual language and text. Any attempt to characterize the study is denied.
5 Defendant denies the remaining allegations in this paragraph of the Complaint.

6 33. The allegations in this paragraph of the Complaint are not directed toward Defendant
7 and, therefore, no response is necessary. Should a response be deemed necessary, Defendant
8 states that the referenced article speaks for itself and respectfully refers the Court to the article
9 for its actual language and text. Any attempt to characterize the article is denied. Defendant
10 denies the remaining allegations in this paragraph of the Complaint.

11 34. The allegations in this paragraph of the Complaint are not directed toward Defendant
12 and, therefore, no response is necessary. Should a response be deemed necessary, Defendant
13 admits that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk
14 Management Advisory Committee was held on February 16-18, 2005. Defendant states that the
15 referenced testimony speaks for itself and respectfully refers the Court to the testimony for its
16 actual language and text. Any attempt to characterize the testimony is denied. Defendant
17 denies the remaining allegations in this paragraph of the Complaint.

18 35. Defendant states that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendant denies any wrongful conduct and
20 denies the remaining allegations in this paragraph of the Complaint.

21 36. Defendant states that the referenced Alert for Healthcare Professionals speaks for itself
22 and respectfully refers the Court to the Alert for Healthcare Professionals for its actual language
23 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
24 Defendant denies the remaining allegations in this paragraph of the Complaint.

25 37. Defendant states that the referenced Alert for Healthcare Professionals speaks for itself
26 and respectfully refers the Court to the Alert for Healthcare Professionals for its actual language
27 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
28 Defendant denies the remaining allegations in this paragraph of the Complaint.

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1 38. Defendant states that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendant denies the allegations in this
3 paragraph of the Complaint.

4 39. Defendant states that the referenced article speaks for itself and respectfully refers the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendant denies any wrongful conduct and denies the remaining allegations in this
7 paragraph of the Complaint.

8 40. The allegations in this paragraph of the Complaint are not directed toward Defendant
9 and, therefore, no response is necessary. Should a response be deemed necessary, Defendant
10 states that the referenced article speaks for itself and respectfully refers the Court to the article
11 for its actual language and text. Any attempt to characterize the article is denied. Defendant
12 denies the remaining allegations in this paragraph of the Complaint.

13 41. Defendant states that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendant states that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendant denies the allegations in this paragraph of the Complaint.

18 42. Defendant states that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendant states that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
23 remaining allegations in this paragraph of the Complaint.

24 43. Defendant states that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendant states that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph

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1 of the Complaint.

2 44. Defendant denies the allegations in this paragraph of the Complaint.

3 45. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed
4 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
5 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
6 admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
7 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
8 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
9 accordance with their approval by the FDA. Defendant states that Bextra® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendant
11 states that the potential effects of Bextra® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendant is without knowledge or information sufficient
14 to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and,
15 therefore, denies the same. Defendant denies any wrongful conduct and denies the allegations
16 in this paragraph of the Complaint.

17 46. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed
18 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
19 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
20 admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
21 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
22 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
23 accordance with their approval by the FDA. Defendant states that Bextra® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendant
25 states that the potential effects of Bextra® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendant denies the remaining allegations in this
28 paragraph of the Complaint.

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1 47. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed
2 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
3 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
4 admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
5 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
6 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
7 accordance with their approval by the FDA. Defendant states that Bextra® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendant
9 states that the potential effects of Bextra® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendant admits, as indicated in the package insert
12 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms
13 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary
14 dysmenorrhea. Defendant denies the remaining allegations in this paragraph of the Complaint.

15 48. Defendant states that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendant states that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which at all times was adequate and comported with applicable standards of care and law.
19 Defendant states that Plaintiff's allegations regarding "predecessors in interest" are vague and
20 ambiguous. Defendant is without knowledge or information to form a belief as to the truth of
21 such allegations, and, therefore, denies the same. Defendant denies any wrongful conduct,
22 denies that Bextra® is defective, and denies the allegations in this paragraph of the Complaint.

23 49. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed
24 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
25 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
26 admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
27 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
28 be prescribed by healthcare providers who are by law authorized to prescribe drugs in

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1 accordance with their approval by the FDA. Defendant states that Bextra® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendant
3 states that the potential effects of Bextra® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendant denies the remaining allegations in this
6 paragraph of the Complaint.

7 50. Defendant states that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendant states that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which at all times was adequate and comported with applicable standards of care and law.
11 Defendant denies the remaining allegations in this paragraph of the Complaint.

12 51. Defendant states that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendant states that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
17 of the Complaint.

18 52. Defendant states that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendant states that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
23 of the Complaint.

24 53. Defendant denies the allegations in this paragraph of the Complaint.

25 54. Defendant admits that the sale of Bextra® was voluntarily suspended in the U.S. market
26 as of April 7, 2005. Defendant denies any wrongful conduct and denies the remaining
27 allegations contained in this paragraph of the Complaint.

28 55. Defendant states that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendant states that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
5 remaining allegations in this paragraph of the Complaint.

6 56. Defendant states that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendant states that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
11 of the Complaint.

12 57. Defendant denies any wrongful conduct and denies the remaining allegations in this
13 paragraph of the Complaint.

14 58. Defendant states that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendant states that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed and co-
19 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
20 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits
21 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
22 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
23 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
24 with their approval by the FDA. Defendant denies any wrongful conduct and denies the
25 remaining allegations in this paragraph of the Complaint.

26 59. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed
27 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
28 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant

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1 admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
2 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
3 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
4 accordance with their approval by the FDA. Defendant denies the remaining allegations in this
5 paragraph of the Complaint.

6 60. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed
7 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
8 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
9 admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
10 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
11 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
12 accordance with their approval by the FDA. Defendant admits, as indicated in the package
13 insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and
14 symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of
15 primary dysmenorrhea. Defendant denies any wrongful conduct and denies the remaining
16 allegations in this paragraph of the Complaint.

17 61. Defendant states that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendant states that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
22 allegations regarding and whether Plaintiff used Bextra® and, therefore, denies the same.
23 Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra®
24 caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
25 Complaint.

26 62. Defendant states that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendant states that the potential effects of
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
3 allegations regarding and whether Plaintiff used Bextra® and, therefore, denies the same.
4 Defendant states that Plaintiff's allegations regarding "predecessors in interest" are vague and
5 ambiguous. Defendant is without knowledge or information to form a belief as to the truth of
6 such allegations, and, therefore, denies the same. Defendant denies any wrongful conduct,
7 denies that Bextra® is defective, denies that Bextra® caused Plaintiff injury or damage, and
8 denies the remaining allegations in this paragraph of the Complaint.

9 **Response to First Cause of Action: Negligence**

10 63. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
11 Complaint as if fully set forth herein.

12 64. Defendant states that this paragraph of the Complaint contains legal contentions to
13 which no response is deemed required. To the extent a response is deemed required, Defendant
14 admits that they had duties as are imposed by law but denies having breached such duties.
15 Defendant states that the potential effects of Bextra® were and are adequately described in its
16 FDA-approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendant states that Bextra® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendant
19 denies the remaining allegations in this paragraph of the Complaint.

20 65. Defendant states that this paragraph of the Complaint contains legal contentions to
21 which no response is deemed required. To the extent a response is deemed required, Defendant
22 admits that they had duties as are imposed by law but denies having breached such duties.
23 Defendant states that Bextra® was and is safe and effective when used in accordance with its
24 FDA-approved prescribing information. Defendant denies the remaining allegations in this
25 paragraph of the Complaint.

26 66. Defendant states that this paragraph of the Complaint contains legal contentions to
27 which no response is required. To the extent that a response is deemed required, Defendant
28 admits that they had duties as are imposed by law but denies having breached such duties.

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1 Defendant states that Bextra® was and is safe and effective when used in accordance with its
2 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
3 were and are adequately described in its FDA-approved prescribing information, which was at
4 all times adequate and comported with applicable standards of care and law. Defendant denies
5 any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint,
6 including all subparts.

7 67. Defendant states that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendant states that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
12 allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
13 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
14 of the Complaint.

15 68. Defendant states that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendant states that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
20 of the Complaint.

21 69. Defendant states that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendant denies any wrongful conduct,
23 denies that Bextra® caused Plaintiff injury or damage, and denies the remaining allegations in
24 this paragraph of the Complaint.

25 70. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
26 damage, and denies the remaining allegations in this paragraph of the Complaint.

27 71. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
28 damage and denies the remaining allegations in this paragraph of the Complaint.

72. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Liability

73. Defendant incorporates by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

74. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same. Defendant admits that Bextra® was expected to reach consumers without substantial change in the condition from the time of sale. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

75. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the allegations in this paragraph of the Complaint.

76. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendant denies that Bextra® is defective or unreasonably dangerous, and denies the
3 remaining allegations in this paragraph of the Complaint.

4 77. Defendant states that this paragraph of the Complaint contains legal contentions to
5 which no response is deemed required. To the extent a response is deemed required, Defendant
6 states that Bextra® was and is safe and effective when used in accordance with its FDA-
7 approved prescribing information. Defendant states that the potential effects of Bextra® were
8 and are adequately described in its FDA-approved prescribing information, which was at all
9 times adequate and comported with applicable standards of care and law. Defendant denies that
10 Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of
11 the Complaint, including all subparts.

12 78. Defendant states that this paragraph of the Complaint contains legal contentions to
13 which no response is deemed required. To the extent a response is deemed required, Defendant
14 states that Bextra® was and is safe and effective when used in accordance with its FDA-
15 approved prescribing information. Defendant states that the potential effects of Bextra® were
16 and are adequately described in its FDA-approved prescribing information, which was at all
17 times adequate and comported with applicable standards of care and law. Defendant denies any
18 wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining
19 allegations in this paragraph of the Complaint.

20 79. Defendant states that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendant states that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra®
25 caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
26 Complaint.

27 80. Defendant states that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendant states that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
4 remaining allegations in this paragraph of the Complaint.

5 81. Defendant is without knowledge or information sufficient to form a belief as to the truth
6 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
7 Defendant states that Bextra® was and is safe and effective when used in accordance with its
8 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
9 were and are adequately described in its FDA-approved prescribing information, which was at
10 all times adequate and comported with applicable standards of care and law. Defendant admits
11 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra®
12 in the United States to be prescribed by healthcare providers who are by law authorized to
13 prescribe drugs in accordance with their approval by the FDA. Defendant admits that, during
14 certain periods of time, Bextra® was manufactured and packaged for Searle, which developed,
15 tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by
16 healthcare providers who are by law authorized to prescribe drugs in accordance with their
17 approval by the FDA. Defendant denies any wrongful conduct, denies that Bextra® is
18 defective, denies that Bextra® caused Plaintiff injury or damage, and denies the remaining
19 allegations in this paragraph of the Complaint.

20 82. Defendant states that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendant states that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendant denies the remaining allegations in this paragraph of the Complaint.

25 83. Defendant is without knowledge or information sufficient to form a belief as to the truth
26 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
27 Defendant states that Bextra® was and is safe and effective when used in accordance with its
28 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®

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1 were and are adequately described in its FDA-approved prescribing information, which was at
2 all times adequate and comported with applicable standards of care and law. Defendant denies
3 the remaining allegations in this paragraph of the Complaint.

4 84. Defendant states that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendant denies any wrongful conduct and
6 denies the remaining allegations in this paragraph of the Complaint.

7 85. Defendant is without knowledge or information sufficient to form a belief as to the truth
8 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
9 Defendant states that Bextra® was and is safe and effective when used in accordance with its
10 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
11 were and are adequately described in its FDA-approved prescribing information, which was at
12 all times adequate and comported with applicable standards of care and law. Defendant denies
13 that Bextra® is defective and denies the remaining allegations in this paragraph of the
14 Complaint.

15 86. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
16 damage, and denies the remaining allegations in this paragraph of the Complaint.

17 87. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
18 damage, and denies the remaining allegations in this paragraph of the Complaint.

19 88. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
20 damage, and denies the remaining allegations in this paragraph of the Complaint.

21 **Response to Third Cause of Action: Breach of Express Warranty**

22 89. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
23 Complaint as if fully set forth herein.

24 90. Defendant is without knowledge or information sufficient to form a belief as to the truth
25 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
26 Defendant states that Bextra® was and is safe and effective when used in accordance with its
27 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
28 were and are adequately described in its FDA-approved prescribing information, which was at

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1 all times adequate and comported with applicable standards of care and law. Defendant admits
2 that they provided FDA-approved prescribing information regarding Bextra®. Defendant
3 denies the remaining allegations in this paragraph of the Complaint.

4 91. Defendant is without knowledge or information sufficient to form a belief as to the truth
5 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
6 Defendant states that Bextra® was and is safe and effective when used in accordance with its
7 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
8 were and are adequately described in its FDA-approved prescribing information, which was at
9 all times adequate and comported with applicable standards of care and law. Defendant admits
10 that they provided FDA-approved prescribing information regarding Bextra®. Defendant
11 denies the remaining allegations in this paragraph of the Complaint, including all subparts.

12 92. Defendant denies the allegations in this paragraph of the Complaint.

13 93. Defendant states that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendant states that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendant admits that they provided FDA-approved prescribing information regarding
18 Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.

19 94. Defendant states that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendant states that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendant admits that they provided FDA-approved prescribing information regarding
24 Bextra®. Defendant denies any wrongful conduct the remaining allegations in this paragraph
25 of the Complaint.

26 95. Defendant is without knowledge or information sufficient to form a belief as to the truth
27 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
28 Defendant admits that they provided FDA-approved prescribing information regarding

1 Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.

2 96. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
3 damage, and denies the remaining allegations in this paragraph of the Complaint.

4 97. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
5 damage, and denies the remaining allegations in this paragraph of the Complaint.

6 98. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
7 damage, and denies the remaining allegations in this paragraph of the Complaint.

8 **Response to Fourth Cause of Action: Breach of Implied Warranty**

9 99. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
10 Complaint as if fully set forth herein.

11 100. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed
12 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
13 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
14 admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
15 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
16 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendant denies the remaining allegations in this
18 paragraph of the Complaint.

19 101. Defendant admits that they provided FDA-approved prescribing information regarding
20 Bextra®. Defendant admits, as indicated in the package insert approved by the FDA, that
21 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
22 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant states
23 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
24 prescribing information. Defendant denies the remaining allegations in this paragraph of the
25 Complaint.

26 102. Defendant is without knowledge or information sufficient to form a belief as to the truth
27 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
28 Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is

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1 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
2 arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining
3 allegations in this paragraph of the Complaint.

4 103. Defendant is without knowledge or information sufficient to form a belief as to the truth
5 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
6 Defendant states that Bextra® was and is safe and effective when used in accordance with its
7 FDA-approved prescribing information. Defendant denies the remaining allegations in this
8 paragraph of the Complaint.

9 104. Defendant is without knowledge or information sufficient to form a belief as to the truth
10 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
11 Defendant states that Bextra® was expected to reach consumers without substantial change in
12 the condition from the time of sale. Defendant denies the remaining allegations in this
13 paragraph of the Complaint.

14 105. Defendant is without knowledge or information sufficient to form a belief as to the truth
15 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
16 Defendant states that Bextra® was and is safe and effective when used in accordance with its
17 FDA-approved prescribing information. Defendant denies any wrongful conduct and denies the
18 remaining allegations in this paragraph of the Complaint.

19 106. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
20 damage, and denies the remaining allegations in this paragraph of the Complaint.

21 107. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
22 damage, and denies the remaining allegations in this paragraph of the Complaint.

23 108. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
24 damage, and denies the remaining allegations in this paragraph of the Complaint.

25 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

26 109. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
27 Complaint as if fully set forth herein.

28 110. Defendant states that this paragraph of the Complaint contains legal contentions to

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1 which no response is deemed required. To the extent a response is deemed required, Defendant
2 admits that they had duties as are imposed by law but denies having breached such duties.
3 Defendant states that Bextra® was and is safe and effective when used in accordance with its
4 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
5 were and are adequately described in its FDA-approved prescribing information, which was at
6 all times adequate and comported with applicable standards of care and law. Defendant denies
7 the remaining allegations in this paragraph of the Complaint.

8 111. Defendant states that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendant states that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
13 of the Complaint, including all subparts.

14 112. Defendant states that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendant states that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
19 of the Complaint.

20 113. Defendant states that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendant states that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably
25 dangerous, and denies the remaining allegations in this paragraph of the Complaint.

26 114. Defendant states that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendant states that the potential effects of
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
3 of the Complaint.

4 115. Defendant denies any wrongful conduct and denies the remaining allegations in this
5 paragraph of the Complaint.

6 116. Defendant is without knowledge or information sufficient to form a belief as to the truth
7 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
8 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
9 of the Complaint.

10 117. Defendant is without knowledge or information sufficient to form a belief as to the truth
11 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
12 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
13 of the Complaint.

14 118. Defendant is without knowledge or information sufficient to form a belief as to the truth
15 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
16 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
17 of the Complaint.

18 119. Defendant denies any wrongful conduct and denies the remaining allegations in this
19 paragraph of the Complaint.

20 120. Defendant is without knowledge or information sufficient to form a belief as to the truth
21 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
22 Defendant states that Bextra® was and is safe and effective when used in accordance with its
23 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
24 were and are adequately described in its FDA-approved prescribing information, which was at
25 all times adequate and comported with applicable standards of care and law. Defendant denies
26 any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

27 121. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
28 damage, and denies the remaining allegations in this paragraph of the Complaint.

1 122. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
2 damage, and denies the remaining allegations in this paragraph of the Complaint.

3 123. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
4 damage, and denies the remaining allegations in this paragraph of the Complaint.

5 **Response to Sixth Cause of Action: Unjust Enrichment**

6 124. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
7 Complaint as if fully set forth herein.

8 125. Defendant admits that, during certain periods of time, Pfizer and Pharmacia marketed
9 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
10 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
11 admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
12 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
13 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
14 accordance with their approval by the FDA. Defendant denies the remaining allegations in this
15 paragraph of the Complaint.

16 126. Defendant is without knowledge or information sufficient to form a belief as to the truth
17 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
18 Defendant denies the remaining allegations in this paragraph of the Complaint.

19 127. Defendant is without knowledge or information sufficient to form a belief as to the truth
20 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
21 Defendant denies the remaining allegations in this paragraph of the Complaint.

22 128. Defendant is without knowledge or information sufficient to form a belief as to the truth
23 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.
24 Defendant states that Bextra® was and is safe and effective when used in accordance with its
25 FDA-approved prescribing information. Defendant denies the remaining allegations in this
26 paragraph of the Complaint.

27 129. Defendant is without knowledge or information sufficient to form a belief as to the truth
28 of the allegations regarding whether Plaintiff used Bextra® and, therefore, denies the same.

1 Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or damage,
2 and denies the remaining allegations in this paragraph of the Complaint.

3 130. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
4 damage, and denies the remaining allegations in this paragraph of the Complaint.

5 **Response to Prayer for Relief**

6 Answering the unnumbered paragraph of the Complaint headed “Prayer for Relief,”
7 Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or damage,
8 and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

9 **III.**

10 **GENERAL DENIAL**

11 Defendant denies all allegations and/or legal conclusions set forth in Plaintiff’s
12 Complaint that have not been previously admitted, denied, or explained.

13 **IV.**

14 **AFFIRMATIVE DEFENSES**

15 Defendant reserves the right to rely upon any of the following or additional defenses to
16 claims asserted by Plaintiff to the extent that such defenses are supported by information
17 developed through discovery or evidence at trial. Defendant affirmatively shows that:

18 **First Defense**

19 1. The Complaint fails to state a claim upon which relief can be granted.

20 **Second Defense**

21 2. Bextra® is a prescription medical product. The federal government has preempted the
22 field of law applicable to the labeling and warning of prescription medical products.
23 Defendant’s labeling and warning of Bextra® was at all times in compliance with applicable
24 federal law. Plaintiff’s causes of action against Defendant, therefore, fail to state a claim upon
25 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
26 and violate the Supremacy Clause of the United States Constitution.

27 **Third Defense**

28 3. At all relevant times, Defendant provided proper warnings, information and instructions

1 for the drug in accordance with generally recognized and prevailing standards in existence at
2 the time.

3 **Fourth Defense**

4 4. At all relevant times, Defendant's warnings and instructions with respect to the use of
5 Bextra® conformed to the generally recognized, reasonably available, and reliable state of
6 knowledge at the time the drug was manufactured, marketed and distributed.

7 **Fifth Defense**

8 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the
9 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendant.

10 **Sixth Defense**

11 6. Plaintiff's action is barred by the statute of repose.

12 **Seventh Defense**

13 7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the
14 Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's
15 damages, if any, are barred or reduced by the doctrines of comparative fault and contributory
16 negligence and by the failure to mitigate damages.

17 **Eighth Defense**

18 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or
19 omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part
20 of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable
21 in any way.

22 **Ninth Defense**

23 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
24 intervening causes for which Defendant cannot be liable.

25 **Tenth Defense**

26 10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were
27 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act
28 of God.

Eleventh Defense

11. Defendant affirmatively denies that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendant or persons acting on its behalf after the product left the control of Defendant.

Seventeenth Defense

17. Plaintiff’s alleged damages were not caused by any failure to warn on the part of

1 Defendant.

2 **Eighteenth Defense**

3 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent
4 conditions unrelated to Bextra®.

5 **Nineteenth Defense**

6 19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the
7 doctrine of assumption of the risk bars or diminishes any recovery.

8 **Twentieth Defense**

9 20. Plaintiff is barred from recovering against Defendant because Plaintiff's claims are
10 preempted in accordance with the Supremacy Clause of the United States Constitution and by
11 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

12 **Twenty-first Defense**

13 21. Plaintiff's claims are barred in whole or in part under the applicable state law because
14 the subject pharmaceutical product at issue was subject to and received pre-market approval by
15 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

16 **Twenty-second Defense**

17 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
18 Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,
19 and Plaintiff's causes of action are preempted.

20 **Twenty-third Defense**

21 23. Plaintiff's claims are barred in whole or in part by the deference given to the primary
22 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
23 issue under applicable federal laws, regulations, and rules.

24 **Twenty-fourth Defense**

25 24. Plaintiff's claims are barred in whole or in part because there is no private right of
26 action concerning matters regulated by the Food and Drug Administration under applicable
27 federal laws, regulations, and rules.

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Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendant's rights to procedural due process under the Fourteenth Amendment of the United States Constitution, the Constitution of the State of Missouri, and the Constitution of the State of California, and would additionally violate Defendant's right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendant.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Missouri and California. Any law, statute, or other authority

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purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendant's conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendant's conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and

any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendant's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the

Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendant states on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendant states on information and belief that any injuries, losses, or damages suffered by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendant. Therefore, Plaintiff's recovery against Defendant, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendant, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Plaintiff's claims are barred by the limitations and defenses set out in the Missouri Product Liability Act, Mo. Rev. Stat. § 537.760 *et seq.*, including but not limited to, the "state of the art" defenses as defined in Mo. Rev. Stat. § 537.764. Defendant incorporates by reference all defenses and/or limitations set forth or referenced in the Missouri Product Liability Act.

Fifty-ninth Defense

59. The proximate cause of the loss complained of by Plaintiff is not due to any acts or

omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable in any way. Mo. Rev. Stat. § 537.765.

Sixtieth Defense

60. The imposition of punitive damages in this case would violate Defendant's rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and Article I, § 17 of the Constitution of the State of Missouri, and would additionally violate Defendant's right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Sixty-first Defense

61. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Missouri law.

Sixty-second Defense

62. Defendant denies that it is liable for any damages in this case. Defendant contends, however, that any damage award to Plaintiff that utilizes the Missouri joint and several liability scheme would be unconstitutional, as this scheme is violative of Defendant's due process and equal protection guarantees under the United States and Missouri Constitutions. The Missouri joint and several liability scheme, under Mo. Rev. Stat. § 537.067, violates Defendant's due process guarantees because no legitimate state interest supports § 537.067, and, furthermore, no rational relationship exists between a legitimate state interest and the promotion of the Missouri joint and several liability scheme. Additionally, the Missouri system of assessing joint and several liability violates Defendant's equal protection guarantees because it operates to create arbitrary classifications of individuals, and to treat similarly situated individuals dissimilarly under the law. The joint and several liability scheme is also unconstitutionally void for vagueness under the United States and Missouri Constitutions. Thus, the scheme is unconstitutional and should not be applied in this action.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Sixty-third Defense

63. Defendant reserves the right to supplement its assertion of defenses as it continue with its factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendant prays for judgment as follows:

1. That Plaintiff takes nothing from Defendant by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendant be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendant in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's injuries and damages; and
6. That Defendant has such other and further relief as the Court deems appropriate.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

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April 2, 2008

GORDON & REES LLP

By: : /s/
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

April 2, 2008

TUCKER ELLIS & WEST LLP

By: : /s/
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendant
PFIZER INC.

JURY DEMAND

Defendant Pfizer Inc. hereby demands a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

April 2, 2008

GORDON & REES LLP

By: : _____/s/
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

April 2, 2008

TUCKER ELLIS & WEST LLP

By:: _____/s/
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendant
PFIZER INC.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111